# Phase II NSF SBIR/STTR Proposal Contents

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# **Cover Sheet**

The cover sheet is automatically generated by FastLane based on information entered into the "Cover Sheet" module and consists of the NSF Cover sheet, Certification, and SBIR Addendum pages.

# **Table of Contents**

The table of contents is automatically generated by FastLane.

# **Project Summary**

The SBIR/STTR Phase II Project Summary has three required sections:

- Overview
- Intellectual Merit
- Broader/Commercial Impact

The aggregate of the three text boxes cannot exceed 4,600 characters. The maximum number of lines that may be included on a page is 51. Information must be entered in each of the three text boxes for FastLane to allow submission of the Project Summary.

Type the "Project Summary", described in more detail below, in the text boxes. When this section is completed, click "Save" and then "Go Back" to return to the "Form Preparation" screen. Information MUST be entered into all three text boxes, or the proposal will not be accepted.

DO NOT use the option (check-box) to upload the Project Summary into the Supplementary Documents unless absolutely necessary, to support "special characters

The Project Summary must have the following components:

- Box 1: Overview, Key Words, and Subtopic Name.
  - o Provide a statement of objectives and methods to be employed.
  - Provide a list of key words or phrases that identify the areas of technical expertise in science, engineering, or education which are to be invoked in reviewing the proposal; and the areas of application that are the initial target of the technology.
  - State the topic name and subtopic letter(s) that the Phase I proposal was submitted under in Phase I.
- Box 2: Intellectual Merit. A summary paragraph addressing the intellectual merits of the proposed activity. The first paragraph of the Intellectual Merit MUST begin with the name of the Program (i.e. "This Small Business Innovation Research Phase II project" or "This Small Business Technology Transfer Phase II project"), as appropriate. No proprietary information should be included in the summary. Include a brief identification of the problem or opportunity, the research objectives, a description of the research, and the anticipated results.
- Box 3: Broader/Commercial Impact. A summary paragraph addressing the broader impacts/commercial potential of the proposed activity. Include information on the potential commercial value, societal impact, and enhanced scientific and technological understanding.

# **Project Description**

The Project Description cannot exceed 15 pages, and all parts must be labeled as presented below. Upload this section (Parts 1-5) as one file. You must first create this file with an editor that outputs Adobe-compatible .PDF files. The project description should contain subsections labeled in the following manner:

## Part 1. Results of the Phase I Project.

Briefly describe how Phase I has established the feasibility of the innovation, provided justification for NSF support and intended commercial applications, and demonstrated the ability of the proposer to conduct R/R&D.

# Part 2. Phase II Technical Objectives, Approach and Work Plan.

Define the specific technical objectives of the Phase II research and technical approach to meet these objectives; and provide a work plan defining specific tasks, performance schedules, milestones, and deliverables. STTR proposals need to specifically address the amount and type of work to be performed both by the small business concern and by the research institution and describe the necessary cooperation, coordination, and complementarity.

# Part 3. Organizational Information.

Consideration is given to the company structure and resources available to successfully complete the Phase II project and to commercialize the results.

Provide a company income statement for the past year detailing revenue from the following:

- Sales
- Licensing
- Contracts
- Consulting
- Other

Provide a current staffing profile noting full and part time employees in the following categories:

- Technical
- Management
- Administrative
- Marketing
- Manufacturing

Briefly summarize future staffing plans.

Identify the key members of the Phase II project team and confirm their specific availability. Specific biographical information should be provided in the Biographical Sketches section of FastLane.

#### Part 4. Consultant and Subaward Agreements.

The proposing small business must perform a minimum amount of the research effort as determined by budget expenditures during Phase II. Under SBIR awards, the proposing small business must perform at least 50% of the research effort. Under STTR awards, the proposing small business must perform at least 40% of the research effort and the cooperating research institute (subaward) must perform at least 30% of the research effort. The proposing small business' research effort, as determined by budget expenditures, does not include consultants (budget line G.3), subawards (budget line G.5) and other costs (budget line G.6).

## All research, including subaward and consultant activities, must be performed in the U.S.

Biographical information is required for all consultants and key members of subawards and should be placed under the Biographical Sketches section of FastLane.

<u>Consultant.</u> Discuss how the requested consultant effort will contribute to the project. Signed consultant agreements must be scanned into the proposal and placed under the Budget Justification. (See budget guidance for Consultants.) The consultant agreement should identify the number of days and its daily rates at which he or she agreed to work.

<u>Subaward</u> (a.k.a. Subcontract). If subawards (including contracts, subcontracts and other arrangements) are used for research, describe the tasks to be performed and how these are related to the overall project. No significant part of the research or substantive effort under a NSF grant may be contracted or

otherwise transferred to another organization without prior NSF authorization. The intent to enter into such arrangements should be disclosed in the proposal. (See budget guidance for Subawards.) Purchases of analytical or other routine services from commercial sources and the acquisition of fabricated components from commercial sources are not regarded as reportable subaward activity. Such items -- routine analytical or other routine services -- should be reported in the Budget under Other Direct Costs/Other (Item G.6). All research, including subaward and consultant activities, must be carried out in the U.S.

# Part 5. Equivalent or Overlapping Proposals to Other Federal Agency.

A firm may elect to submit proposals for essentially equivalent or overlapping work under other Federal program solicitations or may have received or expect to receive other Federal awards for essentially equivalent or overlapping work. In these cases, the proposer MUST inform NSF of related proposals and awards and must first certify on the Proposal Cover page whether the proposer (a) has received Federal government awards for related work, or (b) has submitted currently active proposals for similar work under other Federal government program solicitations or intends to submit proposals for such work to other agencies during the same year. For all such cases, the following information is required:

- The name, address, and telephone contact of the sponsoring agency to which the proposal was (or will be) submitted
- Date(s) of proposal submission(s)
- Title, number, and date of Solicitation under which the proposal was submitted or will be submitted
- Title and performance period of the proposal
- Name and Title of the Principal Investigator effort (person-months (per year) (calendar-months) devoted by any personnel on the equivalent or overlapping project who overlap with PI and personnel on this proposal).

If no equivalent or overlapping proposals are under consideration, state: NONE. NSF will not make awards that essentially duplicate research funded (or expected to be funded) by other agencies, although in some cases NSF may fund portions of work described in an overlapping proposal provided that the budgets appropriately allocate costs among the various sponsors.

IF A PROPOSER FAILS TO DISCLOSE EQUIVALENT OR OVERLAPPING PROPOSALS AS PROVIDED IN THIS SECTION, THE PROPOSER COULD BE LIABLE FOR ADMINISTRATIVE, CIVIL, AND/OR CRIMINAL SANCTIONS.

# **Proposal Budget**

The NSF Summary Proposal Budget is generated in FastLane. Prepare a budget for each year. The system will automatically generate a cumulative budget for the entire project. SBIR/STTR Phase II awards are funded up to \$750,000 for up to 24 months. **Do not submit a proposal budget that exceeds the maximum Phase II amount specified under your Phase I solicitation (\$750,000). Proposals will be returned without review if the budget exceeds this maximum.** 

Budgets for the small businesses will be reviewed against the cost principles of FAR Part 31, as amended by the budget preparation instructions outlined below.

FastLane provides budget justification pages. The proposed costs indicated on the proposal budget

should be consistent with the scope of the research effort and must be based on accurate, complete, and current cost or pricing data. The budget justification documents and justifies the amounts requested in each category. Following is budget preparation guidance:

## Lines A&B: Salaries and Wages.

Only salaries and wages for employees of the proposing organization should be included on Lines A&B. Consultants and subawardee salaries and wages should be budgeted on Lines G.3 and G.5 of the proposal budget, respectively. Research effort is to be estimated in calendar person-months and entered into the column headed by "CAL" (1 CAL = 173 hours) on the Summary Proposal Budget form. CAL effort does not include paid time off and represents actual effort that will be dedicated to the project. *The commitment of the Principal Investigator must be at least 2 months (2 CAL) per year.* Small businesses do not have students and should not propose effort for "students" on Lines B.3 and B.4. (Students are employed by colleges and universities.) Secretarial/clerical effort (Line B.5) is generally included as part of indirect costs. Salaries for secretarial/clerical should be budgeted as a direct cost only if this type of cost is consistently treated as a direct cost in like circumstances for all other project and cost objectives. The circumstances for direct charging secretarial/clerical must be clearly described in the budget justification. Such costs, if not clearly justified, may be deleted by NSF. The budget justification should include individual employee names and titles, effort in units (hours/week/month), unit price, and extended amounts.

# Line C: Fringe Benefits. See Below.

#### Line D: Equipment.

Equipment is defined as nonexpendable, tangible personal property, having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. However, organizations may elect to establish their capitalization threshold as less than \$5,000. Equipment should be budgeted consistently with the proposing organization's capitalization policy. Requests should not be made for general purpose or routine equipment that a business conducting research in the field should be expected to have available. The budget justification must explain the need for any equipment and include the item identification/description, vendor identification, quantity, price, and extended amount.

#### Line E: Travel.

NSF requires that you budget travel (for each year of your proposal) to attend the annual Grantee Conference. A good estimate for the Grantee Conference is \$2,000 per person and is limited to \$4,000 per year. Other than the Grantee Conference, all budgeted travel must be directly related to the research effort and approved by their Program Director. The budget justification must include the destination, purpose of travel, number of days in travel status, and the estimated costs for airfare, cab fare, car rental, per diem rates, hotel and other incidentals. No supporting detail is required for attendance at the Grantee Conference at \$2,000 (or less) per person.

#### Line G.1: Materials and Supplies.

The budget justification must include an itemized listing of materials and supplies to include the item/description, vendor, quantity, price and extended amount.

#### Line G.2: Publication Costs/Documentation/Dissemination.

PIs should discuss possible publication charges with their Program Director.

#### Line G.3: Consultants.

The budget justification must include a signed agreement from each consultant confirming the services to be provided, primary organizational affiliation, number of days committed to the research effort, availability to provide services, and consulting daily rate. The agreement must clearly state the number of days on the project, the consulting daily rate (8 hours/day) and the total dollar amount of the consulting agreement. The consulting daily rate represents the total labor compensation for an 8 hour period and may not exceed \$600 per day. Any miscellaneous costs, such as travel or supplies, that are not included as part of the daily rate must be identified and justified.

# Line G.5: Subawards (a.k.a. Subcontracts).

A separate Summary Proposal Budget with corresponding budget justification must be submitted for each subaward proposed. Line G.5, Subawards, of the proposing organization's Summary Proposal Budget should indicate the dollar amount of all proposed subawards for each year. The proposing organization's budget justification must include the organizational relationship (e.g., common ownership or related parties) between the proposing organization and the subawardee, the type of subaward contemplated (e.g., fixed price or cost reimbursement), and an analysis to support that the subaward budget is reasonable. *Tuition costs are not supported costs under SBIR/STTR subawards to colleges and universities.* The electronic signature policy eliminates the requirement of providing a signed paper copy of the subaward budget; however, it is the responsibility of the proposing organization to confirm that submitted subaward budgets have been approved by an Authorized Organizational Representative at the subawardee organization.

#### Line G.6: Other.

This budget line includes purchases from commercial sources for routine analytical or other services. The budget justification must explain the need for the services, provide a description of the services, and give a detailed breakout of costs.

#### Lines C & I: Fringe and Indirect Costs.

Indirect costs plus fringe benefits is limited to an effective rate of 150% of direct salaries and wages. A budget justification for fringe/indirect costs is not required with the proposal submission. Supporting documentation for fringe/indirect costs will be requested at a later date if your proposal is considered for funding and you have budgeted at an effective rate that exceeds 50% of direct salaries and wages. (Supporting documentation will not be required for indirect costs plus fringe budgeted at an effective rate of 50% or less of direct salaries and wages.) The following expenses will not be funded as part of the indirect cost pools:

- Independent Research and Development (IR&D)
- Patent and patent related expenses will not be funded as either a direct or indirect cost
- Sales and marketing expenses
- Manufacturing and production expenses
- Business development
- Indirect salaries and wages in excess of 35% of total salaries and wages, less paid time off

Note: NSF does not fund Independent Research and Development (IR&D) as part of an indirect cost rate under its grants. IR&D, as defined in FAR 31.205-18(a), includes cost of effort that is not sponsored by a grant or required in performance of a contract and that consists of projects falling within the four following areas: Basic Research, Applied Research, Development, and Systems and other concept formulation studies.

NSF's primary purpose is to support and advance independent research within the scientific and engineering community. NSF has well recognized and established procedures for supporting research through competitive grant awards based on merit review of proposed projects. Reimbursement for independent research and development costs through the indirect cost mechanism could circumvent this competitive process. Accordingly, NSF does not fund IR&D as part of an indirect cost rate under its programs including the SBIR and STTR programs. To ensure that all projects receive similar and equal consideration, eligible organizations may compete for direct funding of independent research projects they consider worthy of support by submitting proposals for those projects to NSF. Because proposals for these projects may be submitted for direct funding, costs for IR&D projects are not allowable as indirect costs under NSF grants.

#### Line K: Fee.

The fee, if requested, is limited to 7%. The 7% fee is allowed only for the proposing small business (No fees are allowed in subaward budgets).

## **Budget Revisions.**

Budget revisions may be requested by the NSF Program Officer. Revised budgets must contain a revised and complete budget justification as described above. Revised budgets with budget impact statements that only address revisions are not acceptable for Phase II budget processing. (See <a href="BUDGET REVISION">BUDGET REVISION</a> INSTRUCTIONS.)

Should your proposal be considered for funding after it is competitively reviewed, the NSF Program Officer will refer you to the Cost Analysis and Audit Resolution (CAAR) Web Site for Phase II Reviews. You will be given 10 calendar days to provide the underlying supporting documentation for your budget. The proposing organization should review and understand the CAAR documentation requirements as it prepares its budget. Once NSF requests the underlying supporting documentation for your budget, you will not be given an opportunity to rebudget unsupported costs. Funding will be provided for only the dollar amount that is reasonable and adequately supported. The awarded Phase II budget will reflect the supported dollar amount for the proposed effort. Organizations that accept awards at less than the proposed dollar amount may not reduce the effort to be provided; however, organizations may choose to decline award offers.

#### References Cited

Provide a comprehensive listing of relevant reference sources, including patent citations.

# **Biographical Sketches**

Provide relevant biographical information for the Principal Investigator and key personnel from the company as well as consultant and key subawardee personnel. Include information on present and past employment, education (highest degree and year), and professional experience. Provide a listing of relevant publications and summarize other contributions to the technical literature not directly pertinent to this proposal.

# **Facilities, Equipment and Other Resources**

Discuss requirements for and the availability of equipment, instrumentation, and facilities required for the Phase II project. If a proposer wants to arrange the use of unique or one-of-a-kind Government facilities, a waiver must be obtained from the Small Business Administration to approve such use.

# **Current and Pending Support**

The proposal should provide information regarding all research to which the Principal Investigator (PI) and other senior personnel either have committed time or have planned to commit time (in the event that other pending projects are supported during the SBIR/STTR Phase II period of performance), whether or not salary for the person involved is included in the budgets of the various projects. If none, state NONE.

For all ongoing or proposed projects, except Equivalent and Overlapping Proposals to Other Federal Agencies, the following information should be provided for the Principal Investigator and senior personnel:

- Name of sponsoring organization
- Title and performance period of the proposal
- Person-months (per year) (calendar months) devoted to the project by the Principal Investigator and each of the senior personnel.

A Current and Pending Support statement should include the Phase II proposal, which is pending at the time of submission.

# **Payment Schedule and Project Milestone Chart**

A payment schedule and a project milestone chart are required components for all Phase II proposals and should be uploaded to FastLane together in a single document.

#### Payment Schedule

Based on the expected utilization of resources and expenditures of funds, if the standard payment schedule as described in the SBIR Phase II General Conditions, Article 6, (CLICK HERE FOR MORE INFORMATION) is not appropriate, provide a list of the number of payments, the percentage amount of each payment, and a brief justification for the departure from the standard schedule. The standard schedule is an initial payment of 25% of the total budget, followed by 3 payments of 20% and a final payment of 15% on submission of the final report. A deviation from the standard payment schedule must be approved by NSF. The final payment of the standard and deviation payment schedules must be 15% of the total budget.

# **Project Milestone Chart**

The milestone (Gantt type) chart must show the duration and timing of major component tasks that are required to implement the research plan. Milestone markings indicating the initiation and completion of tasks should appear clearly in the 24-month time line and in relation to other tasks.

Briefly define each task in terms of how it contributes to the research plan, and describe each milestone event in terms of a concrete accomplishment that marks significant technical progress towards your proposed research objectives.

A sample of a **Phase II MILESTONE CHART** is provided for guidance.

A PHASE II MILESTONE CHART TEMPLATE is also provided.

The original milestone chart should have projected expenditures for each interim reporting period of the project. Resources are defined as follows:

- Level of effort (in person-months) by the PI and/or key personnel (including consultants and subawardees).
- Level of effort (in dollars) by PI and/or key personnel (including consultants and subawardees).
- Permanent equipment (leased or purchased) and/or major purchases of supplies.
- The total expenditures should include a line for "Other", i.e. all project costs including indirect costs.

For each interim reporting period, enter certain key resource expenditures that will be charged against the grant milestones. Reference the Phase II Reporting Requirements for <a href="Interim Progress Reports">Interim Progress Reports</a>.

The original milestone chart should show a complete overview of the proposed project schedule. Actual progress on achieving the milestones along with the person-month effort, and expenditures for each interim reporting period will be required for each reporting period. Each successive interim reporting period will show the progress and expenditure data for all preceding periods as compared to the original plan.

## **Commercialization Plan**

The Commercialization Plan cannot exceed 15 pages, EXCLUDING letters of support.

The Commercialization Plan is a critical section of the proposal. It is the primary opportunity to describe the strategy that your organization will employ to generate revenue from the proposed innovation research. The Commercialization Plan is your roadmap for the future and should convey how you plan to generate profits from your innovation. It should represent a compelling vision that describes a unique business opportunity that could be addressed with continued support from Phase II funding. The depth and quality of the analysis within the Commercialization Plan is a critical element of the NSF SBIR/STTR proposal review. Assumptions within the plan should be clearly stated, and evidence of validation should be provided.

The plan must concisely convey:

- The business opportunity enabled by the innovation
- The compelling value proposition for your intended customer
- The key points of a plan appropriate for your company's stage of development
- The status of the effort to date and map out a strategy for your enterprise moving forward
- The current as well as the anticipated commercial landscape and the resources required to address the opportunity enabled by your innovation
- Your vision for the enterprise and how the proposed innovation fits into the future market.

The outline **below** describes the points that should be covered in a well-developed commercialization plan. There are four sections required for an NSF Commercialization Plan: Market Opportunity, Company/Team, Product/Technology and Competition, Finance and Revenue Model. Each section should be developed with careful analysis of your company's position within the industry and the market opportunity that is enabled by the proposed innovation. The key points required for each section are also shown below.

Note: this outline represents a standard NSF Commercialization Plan. Your particular strategy may include additional components that are not represented below; please include other elements as appropriate.

The National Science Foundation recognizes that each innovation requires a varied strategy to generate returns on invested capital and that no two businesses are exactly alike. Therefore, NSF supports a broad array of commercialization strategies. Each strategy requires varied emphasis on the parts of the plan depending on your innovation and the market landscape. For instance, the strategy and mechanisms for leveraging and protecting intellectual property (IP) vary according to industry and innovation.

# **Market Opportunity**

- Describe succinctly what product or service you are planning to deliver based on your innovation.
- Describe what customer needs will be addressed with your product or service.
- Describe who your target customer is, providing generally-known examples may be helpful.
- How does the target customer currently meet that need that you are addressing or convincingly describe how there is a significant problem that is not yet being addressed?
- What is the business model you plan to adopt to generate revenue from your innovation?
- How do you plan to "exit" the investment?
- Is the target market domestic, international or both?
- Describe the channels you would employ to reach the targeted customer.
- What is the current size of the broad market you plan to enter and the "niche" market opportunity you are addressing?
- What are the growth trends for the market and the key trends in the industry that you are planning to target?
- What are the barriers to enter this market?
- Describe the technology/development objectives and critical milestones that must be met to address the market opportunity.
- If there are potential societal, educational or scientific benefits beyond commercial considerations they should be included here and explained in sufficient detail to convey the significance of the effort.

## Company/Team

- Provide a short description of the origins of the company.
- What type of corporate structure is in place?
- What is the current capitalization?
- What is the current employee count?
- What is the revenue history for the past three years?
- What are the sources of operating capital or revenue: product sales, consulting/services, license revenues, R&D grants/contracts and others?

- Give a brief description of the experience and credentials of the personnel responsible for taking the innovation to market.
- What specific experience does the team lack and how will this be addressed during the Phase II effort and beyond?
- How does the background and experience of the team enhance the credibility of the commercialization plan; have they previously taken similar products/services to market?
- From what additional resources do you have commitment? (e.g., Board of Directors, Board of Advisors, Technical Advisors, Legal Counsel) Provide details on the names, affiliations and expertise of these resources.

# **Product/Technology and Competition**

- What are the critical needs ("pain points") that your product or service is fulfilling for your customer?
- What features of your technology will allow you to provide a compelling value proposition? How have you validated the significance of these features?
- What is your customer willing to pay for your product or service? How have you validated this assumption?
- What are your costs to produce the product or service? What are the assumptions that underlie your cost model(s)?
- How does your technology/innovation allow your team to compete and win in the marketplace?
- How does your product or service match up to that of the competition?
- What do you anticipate the competitive landscape to look like when you get to market?
- Describe the intellectual property landscape.
- Do you have "freedom to operate?"
- How do you plan to protect the intellectual property associated with your technology?
- What other sources of intellectual property will you need to access in order to address the market opportunity described above?

#### **Finance and Revenue Model**

- Describe an appropriate staged finance plan given the market opportunity described above; enumerate the level of funding required for each stage along the path to commercialization.
- How will you access the appropriate funds? Provide specific contacts, leads, previous relationships and agreements already in place.
- What commitments do you have for follow-on funding?
- Describe the revenue streams (licensing, product sales or other) associated with your commercialization plan. What are the adoption rates?
- When do you anticipate "first revenues" from each stream?
- When do you expect to reach "break even"?
- Provide annual pro formas for the next five years (2 years of the Phase II effort + 3 years post Phase II). Income Statements are *required*. Cash Flow and Balance Sheets *may* be included if they are considered critical for your strategy. If not included, Cash Flow and Balance Sheets should be available upon request from NSF.
- What are the assumptions made when developing your models? How have you validated these assumptions?

**N.B.:** Small businesses with NSF SBIR/STTR Phase I awards should actively pursue follow-on funding commitments. If a Phase I award leads to a successful NSF Phase II award, an incentive to the Phase II awardees to pursue non-NSF third party funding is offered in the form of the opportunity to obtain supplemental Phase IIB funding. In order to qualify for the Phase IIB competition, the Phase II awardee must secure and receive third party (private or non-SBIR government) funding during Phase II. The main objective of the Phase IIB Supplement is to extend the R&D efforts beyond the Phase II grant to meet the requirements of a third party investor, to accelerate the Phase II project to the commercialization stage, and/or to enhance the overall strength of the commercial potential of the Phase II project. For more information, please refer to the Phase IIB WEB PAGE.

# **Company Commercialization History**

NOTE -- Please read carefully and respond to questions. This section is a requirement for any proposer who has ever received a Phase II award (from any Federal agency)! Failure to provide complete answers to ALL questions will render the proposal as "non-responsive" and the proposal will be returned without review!

A commercialization history is required for all proposers certifying receipt of Phase II awards on the proposal cover page. All items must be addressed in the format outlined below. Only firms that have received one or more SBIR/STTR Phase II awards from NSF or any other federal agency must submit a company commercialization history. The following are necessary components:

- Firm Name.
- Identify any name change your firm has gone through within the past five years.
- List the parent company if you are a subsidiary or a spin-off. List subsidiaries and spin-offs if you are a parent company.
- Percent of company revenues for each of the past three (3) fiscal years from federal SBIR/STTR funding (includes Phase I and Phase II awards).

List each Phase II SBIR/STTR award and fill out the requested information on the NSF-specific COMMERCIALIZATION FORM.

# **Other Supplementary Documents.**

#### Phase I Final Report or Phase IB Interim Report

Upload a complete copy of your Phase I Final Report or Phase IB Interim Report associated with the Phase II proposal. (Note: The Final Report should not exceed 15 pages.)

## Human Subjects and Vertebrate Animals.

If human subjects Institutional Review Board (IRB) approval is indicated, and it is not in hand at the time of submission, there must be a plan for such approval; a supporting letter regarding IRB approval should be provided under supplementary documents. The approval must be readily attainable within six weeks of informal notification of recommendation for award to ensure continued processing for funding. The small business has three basic options with regard to human subjects review:

 Establish your own IRB (see Office of Human Rights Protection (OHRP) at Health and Human Services (HHS) http://www.hhs.gov/ohrp/assurances/index.html#registernew

- Use the review board of a (usually local) university or research institution, either via consultants to the project, a project subcontract, or directly through its own contacts; and
- Use a commercial company

#### Please refer to Chapter II, Sections D.6 and D.7 of the GPG

(http://www.nsf.gov/publications/pub\_summ.jsp?ods\_key=gpg) for information on the necessary supplementary documents. Note that in some cases, product testing involves human subjects. Look for federal-wide assurances under the Office of Human Research Protection website (http://www.hhs.gov/ohrp/index.html).

Animal use in funded projects requires approval of the company or collaborating institutions' Institutional Animal Care and Use Committee (IACUC). Please refer to <a href="http://www.aphis.usda.gov/">http://www.aphis.usda.gov/</a> for additional information.

## Cooperative Research Agreement (STTR Proposals Only).

If the plan from Phase I is still valid, the Research Institution is required to provide a letter stating this fact. The agreement between the small business concern and the research institution must cover the allocation of intellectual property rights, if any, to carry out follow-on research development, or commercialization. The agreement must contain the signatures of an official of the small business concern and an appropriate official of the research institution.

A <u>MODEL COOPERATIVE RESEARCH AGREEMENT</u> relating to these issues is provided. This model is for guidance only and may be modified by the parties.

When you electronically sign the proposal, the official of the small business concern certifies that the agreement negotiated with the research institution is satisfactory to the small business concern.

#### Postdoc Mentoring Plan.

If the proposal contains a university or similar institution which requests funding for postdoctoral researchers, a postdoc mentoring plan must be included as a supplementary document. *Note that employees of the small business or other for-profit companies DO NOT count as postdocs for this requirement*. More information on this requirement can be found here.

## Data Management Plan.

Proposals must contain a supplementary document labeled "Data Management Plan" which should simply include the statement, "All data generated in this SBIR (or STTR) Phase II project is considered proprietary." FastLane will not permit submission of a proposal that is missing the newly required Data Management Plan. However, the SBIR/STTR Program has received approval for our submitters to simply include the statement above in the Data Management Plan module to enable submission.

## Letter(s) of Support for Technology (no more than 5 letters).

Letters of support act as an indication of market validation for the proposed innovation and add significant credibility to the proposed effort. Letters of support should demonstrate that the company has initiated dialog with relevant stakeholders (potential customers, strategic partners or investors) for

the proposed innovation and that a real business opportunity may exist. The letter(s) must contain affiliation and contact information for the signatory stakeholder. Letters and supporting documents from consultants and subcontractors are NOT considered letters of support and are NOT to be included here. Letters and supporting documents from consultants and subcontractors should be included in the Budget Justification section.